

The Parenteral Drug Association presents:

Best Practices for Glass Primary Containers



SCHOTT
glass made of ideas

**WITH SITE VISIT
AT SCHOTT
TUBULAR GLASS
MANUFACTURING**

12-13 September 2018

InterCityHotel Mainz
Mainz | Germany

WELCOME TO MAINZ



Best Practices for Glass Primary Containers

Overview

Glass vials, ampoules, syringes and cartridges are commonly used in packaging of parenteral pharmaceuticals. Good glass handling practices are essential to assuring glass-based container performance as intended in maintaining the safety and efficacy of the drug product. The two-day course will offer **insights into the science of glass and its inherent properties**. It will review container design and dimensioning, cover glass strength and fracture mechanics as well as review the fundamental principles of good glass handling and inspection. The course will follow step-by-step the processes for packaging of parenterals in vials, ampoules, cartridges and syringes. Further insights into glass breakage including an overview of fracture analysis using fractography will be presented.

Who Should Attend:

- Packaging engineers
- Quality personnel
- Filling line technicians
- Supervisors and engineering support
- Those responding to failure complaints
- Root cause investigators

Prerequisites:

- Technical aptitude
- Some familiarity with pharmaceutical fill/finish processes

Learning Objectives:

Upon completion of the course the participant

- Understands the nature of glass
- Knows what glass breakage causes
- Is aware of regulatory requirements and how to perform QC incoming inspection
- Knows how to inspect glass containers for breakage-relevant defects
- Is able to apply the knowledge to avoid glass breakage in the filling line
- Is able to apply a structured way of evaluating in case of glass breakage
- Is able to 'read' from the splinters and broken glass



Claudia Heinel, PhD, Product Manager Pharmaceutical Tubing, SCHOTT AG

Claudia Heinel studied Chemistry and Biology for teaching profession before she obtained her PhD in Inorganic/Organometallic Chemistry at the University of Regensburg, Germany. In December 2015, she joined the Scientific Services and Product Management team of SCHOTT AG Tubing being responsible for providing global scientific support. This primarily includes glass trainings for converters and pharmaceutical companies, fault analyses of defect samples as well as advice on specific regulations.



Florian Maurer, PhD, Senior Scientist for Strength, Reliability & Lifetime and Fractography at SCHOTT

Florian Maurer earned his doctorate in Materials Science and Engineering in 2007 at Darmstadt University of Technology, Germany. Since then, he has been with SCHOTT with focus on strength, reliability & lifetime and fracture analysis of glass primary packaging containers used in the pharmaceutical industry. Florian and his team provide a powerful toolbox for the identification, characterization and the assessment of flaw-creating mechanisms, which can occur during manufacturing, processing and transportation of glassware.



Karl Siemoneit, PhD, Head Quality Supplier Management, Sanofi-Aventis

Karl Siemoneit is Head of Quality Supplier Management for the Sanofi Insulin manufacturing operations in Frankfurt-Hoechst. This role includes incoming testing and release of primary packaging components such as vials, cartridges and closure components. Karl has over 20 years industrial experience in the IVD / medical device and pharmaceutical industry. He has held various management positions in technical and quality areas. Karl Siemoneit obtained his degree in Biology from the University of Ulm, Germany.



Klaus Ullherr, Senior Product Manager, Robert Bosch GmbH

Klaus Ullherr has a degree in electrical engineering. After university, he worked for several years as a project manager in the electrical industry. In March 2000, he joined Robert Bosch GmbH, Packaging Technology, Product Division Pharma Liquid. During the first two years, he was responsible for handling complex customer orders. Since 2002, he is product manager for the business fields syringes and filling systems with global product responsibility. His main responsibilities are Market Analysis, Initiating New Product Developments, and Business development. He is an expert for syringe processing. He is member of the "PDA Interest Group Pre-filled Syringes" and works as an expert in the DIN/ISO group for primary packaging. He is a popular speaker at conferences covering trends and solutions for fill/finish equipment especially for pre-filled syringes and single-use-filling-systems.

Competition Clause: We ask you for your understanding that participants of competing companies cannot take part in the SCHOTT site visit on 12 September 2018.

Wednesday, 12 September 2018

9:00 – 17:45

9:00 **Welcome and Introduction** All
Participants' Expectations

Manufacture and Characteristics of Glass as Primary Packaging Material

9:15 **Glass Science** Claudia Heintl

- Chemical structure
- Physical properties
- Different glass types in the pharmaceutical industry

10:30 **Coffee Break**

11:00 **Glass Making** Claudia Heintl

- Glass Melting
- Tubing Production
- Container conversion
- Molded containers

12:00 **Lunch Break**

13:00 **Glass Strength and Fracture Mechanics** Florian Maurer

- Glass Breakage - Fundamentals
- Assessment of Flaws
- Fractography - Fundamentals

14:30 **Visit SCHOTT Tubular Glass Manufacturing**



16:00 **Coffee Break**

Receiving Inspection of Glass Primary Packaging Material

16:15 **Requirements from Pharmacopoeias (EP, JP, USP) and Incoming Inspection** Karl Siemoneit

- Overview Pharmacopoeia
- Testing Parameters
- Testing Methods, Equipment, Tools
- Defects and PDA Technical Report #43

17:00 **How to Do in Practice** Karl Siemoneit

- Sampling (AQL)
- Sample size
- Testing
- Documentation
- Supplier certification & test reduction

17:45 **End of Day 1**

Thursday, 13 September 2018
9:00 – 16:00
9:00 Recap of Learning Objectives Day 1

All

Receiving Inspection of Glass Primary Packaging Material (cont.)
9:30 What to Consider, What are the Common Problems, How to Avoid Them

Karl Siemoneit

- Indications for (later) glass breakage | Practical examples

10:15 Coffee Break
10:45 Coordination Process Packaging Manufacturer and Customer

Karl Siemoneit

- Important parameters | Measured variables | Regulating variables | Control loop | Interaction with manufacturer | Effort reduction

Machine Use of Glass Primary Packaging Material
11:15 Machine Runability of Glass Primary Packaging Material

Klaus Ullherr

- Roughness of glass primary packaging material | Geometrics, tolerances | Quality of glass | Impact of machine speed

11:45 Lunch Break
12:45 Use of Glass Primary Packaging Material Along the Process Chain

Klaus Ullherr

Considering different kind of containers, bulk and nested:

- Washing machine | Depyrogenation tunnel | Filling machines | Stoppering | Rod insertion and labelling for syringes | Conveyor belts | Automated inspection | Packaging line

13:30 Case Study

Klaus Ullherr

What to Consider, What are Common Problems, How to Avoid Them

- Collision analysis
- Basics of good glass handling
- Technologies to avoid glass to glass contact

14:15 Coffee Break
14:45 Coordination Process Primary Packaging Material and Machine

Klaus Ullherr

- Important parameters | Control loop | Synchronization

15:30 Q & A

All

16:00 Summary & End of Training Course

VENUE

InterCityHotel Mainz

Binger Strasse 21
55131 Mainz | Germany
Tel: +49 696 65 64-460

Special rates

PDA Europe has reserved a limited number of bedrooms until the 13 July 2018. Book your group rate for PDA.

Room 179€ per room and night.

Housing at the selected hotel will be in high demand, so we strongly recommend making your reservations early.

DIRECTIONS

© Google For directions click on the picture, scan the QR-code or go to <https://goo.gl/maps/QSVuG3xC4xT2>

CONTACT INFORMATION

Registration Customer Care

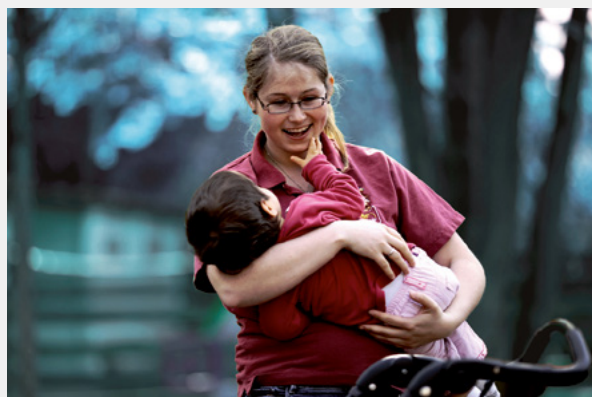
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PDA Europe supports the children's hospice „Sonnenhof“

The Sonnenhof Hospice, located near PDA's office in Berlin, offers support and assistance to families with children suffering from incurable and/or debilitating diseases. At Sonnenhof, children, together with their families, can spend the time they have left as they wish and find some relief from their suffering. Instead of purchasing expensive gifts for the conference speakers, PDA has decided to donate this amount to the Sonnenhof Hospice. You can also contribute and help us increase the amount, it is easy:

buy a package of chewing gums at the registration desk. THANK YOU!

To know more about the Sonnenhof Hospice, please visit www.bjoern-schulz-stiftung.de

Björn Schulz 
STIFTUNG
Für eine Zeit voller Leben

3 WAYS TO REGISTER

- 1 **ONLINE:** pda.org/EU/GPC2018
- 2 **FAX:** +49 30 4365508-66
- 3 **EMAIL:** registration-europe@pda.org

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

1 Your Contact Information

If this form is an update to a previously submitted form, please check here.

Mr. Ms. Dr. Nonmember I want to become a PDA Member. Please send me a subscription form
 PDA Member ID Number

Name (Last, First, MI) *

Job Title *

Company* Department

Mailing Address

City Postal Code

Country Email *

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Substituting for

(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

2 Registration

Two-Day Training Course (12-13 September) Best Practices for Glass Primary Containers

All Participants **1495**

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation.

Statement by SCHOTT / Competition Clause:

We ask you for your understanding that participants of competing companies cannot take part in the site visit on 12 September 2018.

Registration Deadline: 5 September 2018

3 Payment Options

By Credit Card

American Express MasterCard VISA

For your credit card information safety:
 Please send your details by fax only (+49 30 4365508-66) or register online.

By Bank Transfer

Beneficiary: PDA Europe gGmbH
IBAN: DE73 1007 0024 0922 8735 00
BIC (SWIFT-Code): DEUTDE33
Bank Address: Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

By Purchase Order Purchase Order Number

PDA Europe VAT I.D.: DE254459362

Billing Address: Same as contact information address above. If not, please send your billing address to: registration-europe@pda.org

Your Company VAT I.D.:

This number starts by your country code with two characters
 (example: PDA Europe's country code starts with: DE | followed by the number)

Date Mandatory Signature

CONFIRMATION: Transmitting your filled-in registration form constitutes a binding application for the specific event. PDA Europe will send you a confirmation including payment details. **A legally binding contract is concluded once PDA Europe has sent a written invoice by mail to you.** A letter of confirmation will be sent to you within one week once payment has been received. You must have this written confirmation to be considered enrolled for this PDA event. PDA Europe reserves the right to deny access to anyone unable to provide written confirmation that all dues have been fully settled. **SUBSTITUTIONS:** If you are unable to attend, substitutions are welcome and can be made at any time, including on site at the prevailing rate. If you are registering as a substitute attendee, please indicate this on the registration form. Changes are free of charge until 2 weeks prior to the start of the event. After this two-weeks period, there will be a charge of € 100 excl. VAT per name change. **REFUNDS: Refund requests must be sent to PDA Europe.** If your written request is received on or before **12 August 2018** you will receive a full refund minus a 150 € excl. VAT handling fee. After that time, no refund or credit requests will be approved. If you are an unpaid registrant and do not attend the event, you are responsible for paying the registration fee. On-site registrants are not guaranteed to receive conference materials until all advanced registered attendees receive them. PDA Europe works PCI-Compliant. **EVENT CANCELLATION:** PDA reserves the right to modify the material or speakers/instructors without notice, or to cancel an event. If an event must be canceled, registrants will be notified by PDA as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancellation. For more details, contact PDA at registration-europe@pda.org or fax to +49 30 4365508-66. **DOCUMENTATION:** With your signature you give complete picture usage right to PDA and allow to film your exhibition space and intervention in the event, including the recording of your presentation for video purposes (with your slides, voice and image). This right extends also to the use of the resulting images in film documentation for webinars and similar items produced by PDA.

2018 PDA EUROPE EVENTS

13 April	Interest Group Meeting Visual Inspection	IG Berlin, Germany
24-25 April	Vaccines	Málaga, Spain
8-9 May	Virus Forum	Florence, Italy
29-30 May	Pharmacopoeia Conference	Vienna, Austria
5-6 June	Advanced Therapy Medicinal Products	* Amsterdam, The Netherlands
25 June	Interest Group Meeting Quality Systems	IG
25 June	Interest Group Meeting Freeze Drying	IG
26-27 June	3rd PDA Europe Annual Meeting	* Berlin, Germany
15-16 October	Pharmaceutical Microbiology	* Berlin, Germany
23-24 October	Visual Inspection Forum	* Berlin, Germany
6-7 November	Outsourcing & Supply Chain - A 360° View	* Seville, Spain
22 November	Project Management in the Pharmaceutical Industry – Challenges & Possibilities	* Berlin, Germany
27-28 November	Pharmaceutical Freeze Drying Technology	* Seville, Spain
27-28 November	11 th Workshop on Monoclonal Antibodies	* Seville, Spain

Subject to change

For latest info: europe.pda.org

Shortlist 20 Feb 2018

* Events with additional Education Program. More information – europe.pda.org



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